10/632,101

IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: U.S. Patent No. 7,423,055 Attorney Docket No.: 71247-0144

Issued: September 9, 2008

Inventors: Ciufolini, et al.

Assignee: AB SCIENCE

For: 2-(3-Aminoaryl)Amino 4-Arylthiazoles For The Treatment Of Diseases

MAIL STOP PATENT EXTENSION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATION FOR THE EXTENSION OF THE TERM OF THE UNITED STATES PATENT NO. 7,423,055 UNDER 35 U.S.C. § 156

Sir:

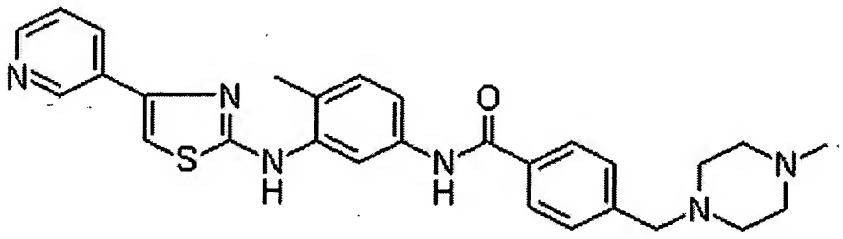
In accordance with 35 U.S.C. § 156 and 37 C.F.R. § 1.740, AB Science, a corporation of France, ("AB Science"), through the undersigned, represents that it is the owner of record of United States Patent No. 7,423,055 ("the '055 patent"), attached hereto as Exhibit A, and hereby requests an extension of the patent term thereof. A copy of the assignment and assignment recordation from the '055 patent, which were recorded on January 12, 2004 at Reel 014872, Frame 0028 confirming that all right, title, and interest resides in AB Science, is attached hereto as Exhibit B.

The following information is submitted in accordance with 35 U.S.C. § 156(d) and 37 C.F.R. § 1.740. The sections of this application are numbered in a manner corresponding with

the numbering of subparagraphs (1) to (15) of 37 C.F.R. § 1.740(a) and follow the format set forth therein.

(1) "A complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics."

The approved product is sold under the trade name KINAVET-CA1, the active ingredient of which is masinitib. A chemical name of masinitib is 4-(4-Methyl-piperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-4-yl-thiazol-2-ylamino)-phenyl]-benzamide, and the structure is shown below:



Synonyms for masinitib include AB1010, MM, and KINAVET. The molecular weight of masinitib is 498.67 g/mol, and its empirical formula is $C_{28}H_{30}N_6OS$. (*See* Product Label , Exhibit C, page 1).

As currently approved, the product sold under the trade name KINAVET-CA1 is indicated for the treatment of recurrent (post-surgery) or nonresectable Grade II or III cutaneous mast cell tumors in dogs that have not previously received radiotherapy and/or chemotherapy except corticosteroids in dogs. (*See* Product Label, Exhibit C, page 1). Currently, the approved product is available in the form of a tablet for oral administration. (*See* Product Label, Exhibit C, page 1).

(2) "A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred."

The product sold under the trade name KINAVET-CA1 (masinitib) was subject to regulatory review for an investigational new animal drug application ("INAD") and a conditional

new animal drug application ("NADA") under section 571(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 360ccc(b) ("FFDCA"). Section 571(b) authorizes the conditional approval of an application pending the full demonstration of effectiveness under section 512(d)(1)(E) (21 U.S.C. § 360b(d)(1)(E)) within 5 years. The Food and Drug Administration ("FDA") approved the KINAVET-CA1 product (conditional NADA 141-308) under the authority granted by section 571(b) of the FFDCA, 21 U.S.C. § 360ccc(b).

(3) "An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred."

The product sold under the trade name KINAVET-CA1 (masinitib) conditionally received permission for commercial marketing or use from the FDA pursuant to section 571(b) of the FFDCA, 21 U.S.C. § 360ccc(b), on December 15, 2010. According to the approval received from the FDA, the application is conditionally approved for one year from December 15, 2010 and is renewable annually for up to four additional one-year terms upon demonstration that Applicant is making sufficient progress toward meeting the approval requirements under section 512(d)(1)(E) of the FFDCA, the quantity of the drug distributed is consistent with the conditionally intended use, and the same drug in the same dosage form for the same intended use has not received approval under Section 512. Copies of the Product Label and FDA conditional approval letter are attached as Exhibits C and D, respectively.

(4) "In the case of a drug product, an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, or the Virus-Serum- Toxin Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients), the use for which it was approved, and the provision of law under which it was approved."

The active ingredient in the product sold under the trade name KINAVET-CA1 is masinitib. Masinitib has not been previously approved for commercial marketing or use under the FFDCA, the Public Health Service Act or the Virus-Serum-Toxin Act.

(5) "A statement that the application is being submitted within the sixty day period permitted for submission pursuant to § 1.720(f) and an identification of the last day on which the application could be submitted."

This application is being submitted within the sixty days from receipt of the conditional approval under Section 571 of the FFDCA from the FDA. To the extent Section 571 of the FFDCA can serve as a basis for patent term extension, this application is being submitted within the sixty day period permitted for submission pursuant to 37 C.F.R. § 1.720(f), the last day for said submission being February 12, 2011.

(6) "A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration."

The complete identification of the patent for which extension is sought is as follows:

Inventors:	Marco Ciufolini, Camille Wermuth, Bruno Gielthen, and Alain Moussy
Patent No.:	7,423,055
Issue Date:	September 9, 2008
Expiration Date:	August 1, 2023

(7) "A copy of the patent for which an extension is being sought including the entire specification (including claims) and drawings."

A copy of U.S. Patent No. 7,423,055 ("the '055 patent"), for which this extension is sought, is attached hereto as Exhibit A.

(8) "A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or re-examination certificate issued in the patent."

A copy of the terminal disclaimer filed and received at the United States Patent and Trademark Office on April 10, 2008, which disclaims the terminal part of the '055 patent extending beyond the expiration of U.S. Patent Application No. 11/779,633, is attached hereto as Exhibit E.

No reexamination certificate for the '055 patent was issued.

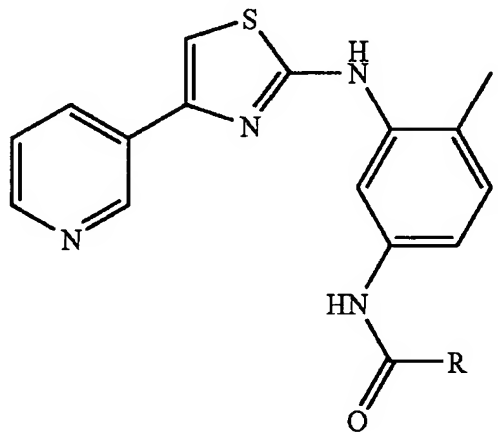
The first maintenance fee payment is not due until March 9, 2012 so no maintenance fee payment receipt is available.

(9) "A statement that the patent claims the approved product or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim

and demonstrates the manner in which at least one such patent claim reads on: (i) The approved product, if the listed claims include any claim to the approved product; (ii) The method of using the approved product, if the listed claims include any claim to the method of using the approved product; and (iii) The method of manufacturing the approved product, if the listed claims include any claim to the method of manufacturing the approved product."

The '055 patent claims, *inter alia*, a composition of the approved product, *e.g.* the active ingredient of the product sold under the trade name KINAVET-CA1. More specifically, at least claims 1, 5, 7-10, 13-18, and 20 of the '055 patent read on the approved product. Claims 1, 5, 7-10, 13-18, and 20 are set forth below along with a showing as to how the claims read on the approved product:

Claim 1. A compound according to the following formula:

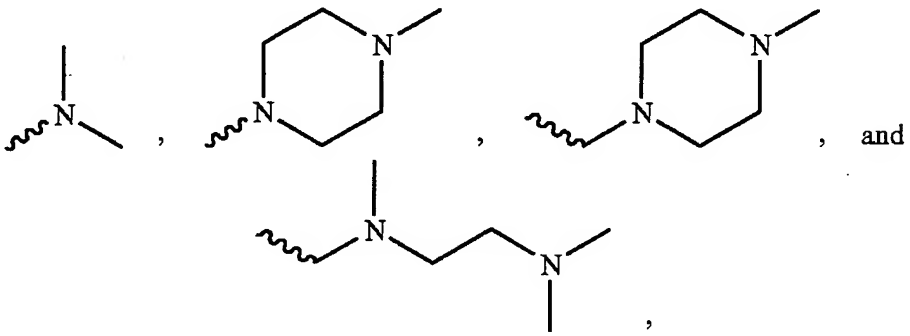


wherein R is:

H or a linear or branched alkyl group containing from 1 to 10 carbon atoms optionally substituted with at least one substituent selected from the group consisting of halogen and a pendant basic nitrogen functionality; or

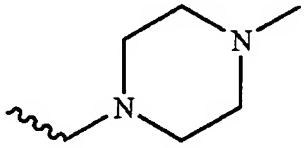
a cycloalkyl, an aryl or heteroaryl group optionally substituted by an alkyl, a cycloalkyl, an aryl or heteroaryl group optionally substituted with at least one substituent selected from the group consisting of a halogen and a pendant basic nitrogen functionality;

wherein said pendent basic nitrogen functionality is selected from the group consisting of



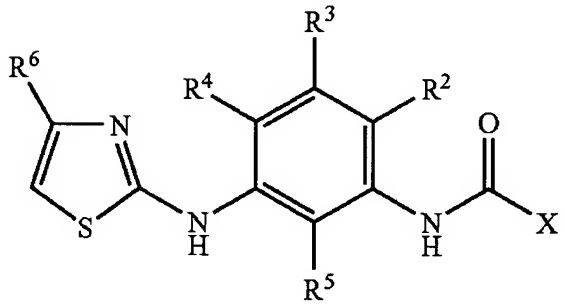
wherein the wavy line corresponds to the point of attachment.

Claim 1 reads on the approved product when
R=aryl substituted by a pendant basic nitrogen functionality which is

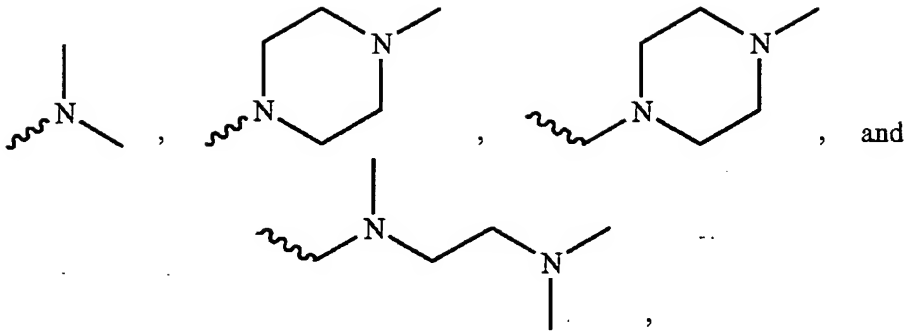


Claim 5. A compound according to formula II:

FORMULA II



wherein X is R or NRR′ and wherein R and R′ are independently chosen from H, an aryl, an heteroaryl, an alkyl and a cycloalkyl group optionally substituted with at least one substituent selected from the group consisting of a halogen and a pendant basic nitrogen functionality;
an aryl, an heteroaryl, an alkyl and a cycloalkyl group substituted with an aryl, an heteroaryl, an alkyl and a cycloalkyl group optionally substituted with at least one substituent selected from the group consisting of a halogen and a pendant basic nitrogen functionality;
wherein said pendant basic nitrogen functionality is selected from the group consisting of



wherein the wavy line corresponds to the point of attachment;

R^2 is hydrogen, halogen or a linear or branched alkyl group containing from 1 to 10 carbon atoms, trifluoromethyl or alkoxy;

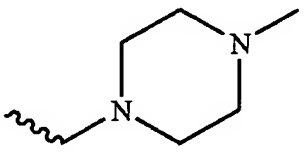
R^3 is hydrogen, halogen or a linear or branched alkyl group containing from 1 to 10 carbon atoms, trifluoromethyl or alkoxy;

R^4 is halogen or a linear or branched alkyl group containing from 1 to 10 carbon atoms, trifluoromethyl or alkoxy;

R^5 is hydrogen, halogen or a linear or branched alkyl group containing from 1 to 10 carbon atoms, trifluoromethyl or alkoxy;

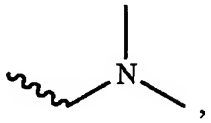
R^6 is one of the following:
(i) an aryl group optionally substituted by one or more substituents such as halogen, alkyl groups containing from 1 to 10 carbon atoms, trifluoromethyl, or alkoxy;
(ii) a heteroaryl group such as a 2, 3, or 4-pyridyl group, which may additionally bear one or more substituents;
(iii) a five-membered ring aromatic heterocyclic group such as for example 2-thienyl, 3-thienyl, 2-thiazolyl, 4-thiazolyl, or 5-thiazolyl, which may additionally bear one or more substituents.

Claim 5 reads on the approved product when
R^2,R^3,R^5 = hydrogen
R^4= methyl (alkyl with 1 carbon atom)
R^6= 3-pyridyl group
X= R wherein R is aryl substituted by a pendant basic nitrogen functionality which is

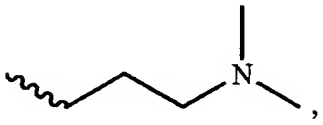


Claim 7. A compound according to claim 5, wherein X is selected from the structures (a)-(d) and (f) shown below:

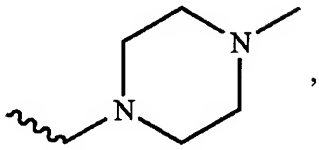
a



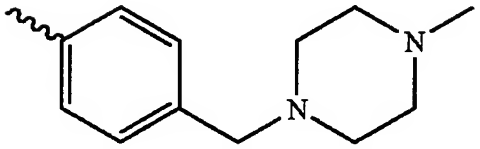
b



c

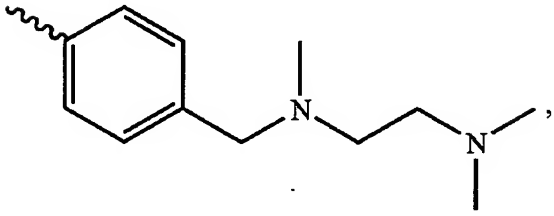


d



, or

f



wherein the wavy line corresponds to the point of attachment to core structure of formula II.

Claim 7 reads on the approved product when
X= structure d),
R^2,R^3,R^5 =Hydrogen,
R^4= methyl (alkyl with 1 carbon atom) and
R^6= 3-pyridyl group.

Claim 8. A compound according to claim 7, wherein X is group (d) and R^6 is a 3-pyridyl group.

Claim 8 reads on the approved product when
R^2,R^3,R^5 =hydrogen, and

R^4= methyl (alkyl with 1 carbon atom).

Claim 9. A compound according to claim 7, wherein X is group (d) and R^4 is a methyl group.

Claim 9 reads on the approved product when
R^2,R^3,R^5 =hydrogen, and
R^6= 3-pyridyl group.

Claim 10. A compound according to claim 7, wherein X is group (d) and R^2 and/or R^3 and/or R^5 is H.

Claim 10 reads on the approved product when
R^2,R^3,R^5 =hydrogen,
R^4= methyl (alkyl with 1 carbon atom), and
R^6= 3-pyridyl group.

Claim 13. The compound of claim S which is: 4-(4-methyl-piperazin-i -yl)-N-[4-methyl-3-(4-pyridin-3-yl-thiazol-2-ylamino)-phenyl]-benzamide (example 060) or 4-(4-methylpiperazin-1 -ylmethyl)-N-[4-methyl-3-(4-pyridin-3-ylthiazol-2-ylamino)-phenyl] -benzamide (example 066).

Claim 13 reads on the approved product since it presents two alternative compounds, the latter one describing a chemical compound 4-(4-Methyl-piperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-4-yl-thiazol-2-ylamino)-phenyl]-benzamide, which encompasses the methanesulfonate-containing active ingredient of the approved product.

Claim 14. A compound which is: 4-(4-methyl-piperazin-1 –ylm-ethyl)-N-[4-methyl-3-(4-pyridin-3-yl-thiazol-2-ylamino)-phenyl]-benzamide (example 066).

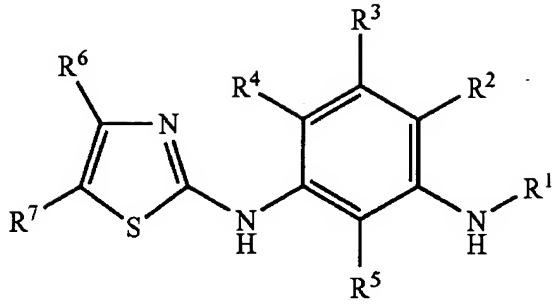
Claim 14 specifically claims the latter alternative of claim 13 and reads on the approved product for the same reason as set forth above for claim 13.

Claim 15. A composition comprising a compound of claim 14 and a pharmaceutically acceptable carrier.

Claim 15 reads on the approved product since the approved product, which is covered by claim 14, is in a pharmaceutically acceptable carrier.

Claim 16. A compound of formula I:

FORMULA I



wherein R^1 is:-C(O)R, -C(O)OR, or –CO-NRR′, wherein R and R′ are independently selected from the group consisting of hydrogen, aryl, heteroaryl, alkyl, and cycloalkyl, each optionally substituted with at least one substituent selected from the group consisting of halogen and a pendant basic nitrogen functionality;

R^2 is hydrogen, halogen or a linear or branched alkyl group containing from 1 to 10 carbon atoms, trifluoromethyl or alkoxy;

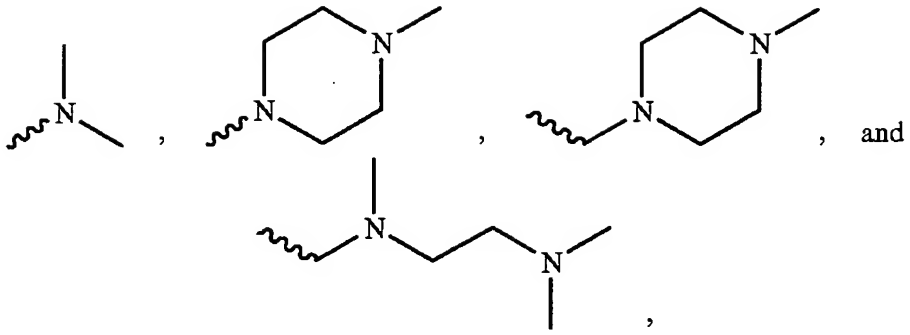
R^3 is hydrogen, halogen or a linear or branched alkyl group containing from 1 to 10 carbon atoms, trifluoromethyl or alkoxy;

R^4 is halogen or a linear or branched alkyl group containing from 1 to 10 carbon atoms, trifluoromethyl or alkoxy;

R^5 is hydrogen, halogen or a linear or branched alkyl group containing from 1 to 10 carbon atoms, trifluoromethyl or alkoxy;

R^6 is one of the following:(i) an aryl group such as phenyl optionally substituted by one or more substituents such as halogen, alkyl groups containing from 1 to 10 carbon atoms, trifluoromethyl, or alkoxy;(ii) a heteroaryl group such as a 2, 3, or 4-pyridyl group, which may additionally bear one or more substituents; or(iii) a five-membered ring aromatic heterocyclic group such as for example 2-thienyl, 3-thienyl, 2-thiazolyl, 4-thiazolyl, or 5-thiazolyl, which may additionally bear one or more substituents;

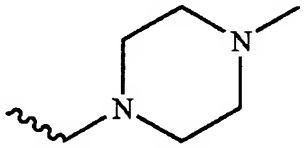
and R^7 is one of the following:(i) an aryl group such as phenyl optionally substituted by one or more substituents;(ii) a heteroaryl group such as a 2, 3, or 4-pyridyl group, which may additionally bear one or more substituents;(iii) a five-membered ring aromatic heterocyclic group such as for example 2-thienyl, 3-thienyl, 2-thiazolyl, 4-thiazolyl, or 5-thiazolyl, which may additionally bear one or more substituents; or(iv) H, a halogen selected from I, F, Cl or Br; NH_2, NO_2 and SO_2-R″, wherein R″ is a linear or branched alkyl group optionally substituted with at least one substituent selected from the group consisting of halogen and a pendant basic nitrogen functionality; wherein said pendant basic nitrogen functionality is selected from the group consisting of



wherein the wavy line corresponds to the point of attachment.

Claim 16 reads on the approved product when

R1= -C(O)R wherein R is aryl substituted by a pendant basic nitrogen functionality which is

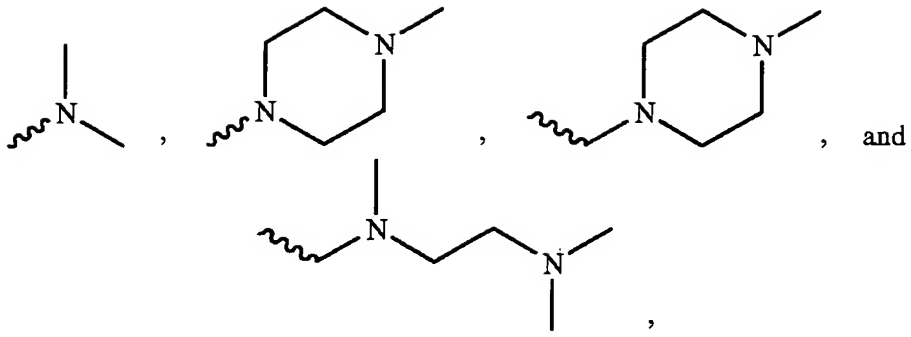


R^2,R^3,R^5 =hydrogen,
R^4= methyl (alkyl with 1 carbon atom), and
R^6= heteroaryl (3-pyridyl group).

Claim 17. A composition comprising a compound of claim 16 in a pharmaceutically acceptable carrier.

Claim 17 reads on the approved product since the approved product, which is covered by claim 16, is in a pharmaceutically acceptable carrier.

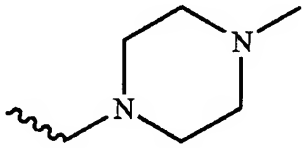
Claim 18. A compound according to claim 16, wherein R' is C(0)R, wherein R is independently selected from the group consisting of hydrogen, aryl, heteroaryl, alkyl, and cycloalkyl, each optionally substituted with at least one substituent selected from the group consisting of halogen and a pendant basic nitrogen functionality; wherein said pendant basic nitrogen functionality is 60 selected from selected from the group consisting of



wherein the wavy line corresponds to the point of attachment.

Claim 18 reads on the approved product when

R1 (not R') is -C(O)R wherein R is aryl substituted by a pendant basic nitrogen functionality which is



Claim 20. A pharmaceutical composition comprising a compound according to claim 18 and a pharmaceutically acceptable carrier.

Claim 20 reads on the approved product since the approved product, which is covered by claim 18, is in a pharmaceutically acceptable carrier.

(10) "A statement, beginning on a new page, of the relevant dates and information pursuant to 35 U.S.C. § 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period as follows:

...(ii) For a patent claiming a new animal drug:

(A) The date a major health or environmental test on the drug was initiated, and any available substantiation of that date, or the date of an exemption under subsection (j) of Section 512 of the Federal Food, Drug, and Cosmetic Act became effective for such animal drug;

(B) The date on which a new animal drug application (NADA) was initially submitted and the NADA number; and

(C) The date on which the NADA was approved".

The relevant dates and information pursuant to 35 U.S.C. § 156(g) to enable the Secretary of Health and Human Services to determine the applicable regulatory review period for the product sold under the trade name KINAVET-CA1 are as follows:

(a) A letter dated March 11, 2004 from the FDA administratively assigned Investigational new animal drug ("INAD") application number 011206. (Attached as Exhibit H). A Notice of Claimed Investigational Exemption (NCIE) for a New Animal Drug was filed with the FDA on February 1, 2005. (Attached as Exhibit I). In addition, studies relevant to the conditional approval for the product sold under the trade name KINAVET-CA1 were conducted as early as April 2003, e.g., 4-Week Toxicity Study described in Section III, B of the Freedom of Information Summary attached in Exhibit G. Accordingly, Applicant believes that the date a major health or environmental test on the drug was initiated or the date of an exemption under subsection (j) of section 512 of the FFDCA is at least on or around February 1, 2005, if not earlier.

Although Applicant may be entitled to an earlier date under 37 C.F.R. § 1.740(a)(10)(ii)(A), for the purposes of calculating the patent term extension of the '055 patent based on the conditional approval of conditional NADA application 141-307 under Section 571(b) herein, Applicant will use February 1, 2005. Applicant notes that this date is well before September 9, 2008, the issue date of the '055 patent, and that 37 C.F.R. §1.778(d)(1)(i) requires subtraction from the patent term extension calculations the number of days on and before the date the patent issued. (b) The conditional new animal drug application under Section 571 was submitted on July 9, 2010 for conditional approval, and was assigned conditional NADA

number 141-308.

(c) Conditional NADA number 141-308 was conditionally approved by the FDA on December 15, 2010 (Exhibit D).

(d) According to the approval letter received from the FDA, the conditional application is conditionally approved for one year, which will expire on December 15, 2011. However, the conditional application is renewable annually for up to four additional one-year terms upon filing a request to renew this application within 90 days from the end of the one-year period demonstrating that Applicant is making sufficient progress toward meeting the approval requirements under section 512(d)(1)(E) of the FFDCA, the quantity of the drug distributed is consistent with the conditionally intended use, and the same drug in the same dosage form for the same intended use has not received approval under Section 512.

(11) "A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities."

A chronology of selected regulatory activities is attached hereto as Exhibit F to briefly describe certain activities undertaken with respect to the approval of the product under the trade name KINAVET-CA1 during the applicable regulatory review period and the dates applicable to such activities. Also attached as Exhibit G is the Freedom of Information Summary, which details the various tests conducted in connection with the regulatory review period.

(12) "A statement beginning on a new page that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of the extension claimed, including how the length of extension was determined."

Applicant respectfully submits that 35 U.S.C. § 156 and the associated regulations do not clearly address whether a product reviewed under Section 571 of the FFDCA would be eligible for patent term extension. Applicant is unaware of any prior decisions by the USPTO or the FDA addressing this particular issue and believes that this is one of first impression for these regulatory agencies. Pursuant to § 156(d)(1), a patent term application "may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use." Therefore, Applicant submits this application within 60 days of receiving the FDA's conditional approval of KINAVET-CA1 (conditional NADA 141-308) to request administrative review whether conditional approval of an animal drug under Section 571 of the FFDCA can serve as a basis for patent term extension. If so, Applicant respectfully requests for an extension of **493 days**, the calculation of which is further described below. Should the delays based on regulatory review under Section 571 not be eligible for patent term extension under 35 U.S.C. § 156(g), then Applicant respectfully submits that a subsequent regulatory approval of KINAVET-CA1 under Section 512(b) should be considered as "the first permitted commercial marketing or use of the product" as required by § 156(a)(5)(A) and reserves the right to file a subsequent patent term extension application based on subsequent express approval under Section 512(b).

The conditional NADA application under Section 571(a) of the FFDCA is an alternative regulatory process to authorize the distribution and commercial marketing of new animal drugs "intended for a minor use or a minor species," instead of the so-called "traditional" NADA under Section 512 of the FFDCA. Pursuant to the statute, conditional NADA applications under Section 571(a) "must comply in all respects with the provisions of section 512 of this Act" except for certain statutorily exempt sections. In particular, the statute states that "[n]ew animal drugs are subject to application of the same safety standards that would be applied to such drugs under section 512(d) (including, for antimicrobial new animal drugs, with respect to antimicrobial resistance)." 21 U.S.C. §360ccc(a)(1). Consistent with the language of the statute, and the FDA's guidelines regarding minor use and minor species animal drug applications, the

conditional approval issued under section 571(b) of the Federal Food, Drug, and Cosmetic "provides for animal drug marketing after all safety and manufacturing components of a new animal drug approval have met the standards of section 512 of the act (for the effectiveness component, a reasonable expectation of effectiveness must be established, after which sponsors have up to 5 years to complete the demonstration of effectiveness by the standards of section 512 of the act and achieve a full approval)." 70 Fed. Reg. 56394 (Sept. 27, 2005).

In addition to incorporating the substantive requirements of Section 512 of the FFDCA, the regulatory approval process under Section 571 is closely integrated with the statutory process under Section 512. Most notably, Section 512(b)(3) specifically incorporates a process for "[a]ny person intending to file an application under paragraph (1), section 571" to obtain one or more conferences with the FDA prior to submission of the conditional NADA. Applicant also notes that Section 512 refers to a conditional approval of an application filed pursuant to Section 571 as one possible route for an animal drug to be reviewed and deemed safe by the FDA. See 21 USC § 360b(a)(1)(B) and (a)(2)(A)(ii). Section 512(f), (g), (i), (l)(1) and (p)(1) provide identical review and record keeping processes for both Section 512 and Section 571 applications including: process for addressing decisions refusing, withdrawing or suspending approval; process for granting an order; process for publication in the Federal Register; requirements for record keeping and requirements for public access to safety and effective data.

In light of the integrated approval provisions of Sections 512 and 571 and the specific procedure established in Section 512(b) for initiating Section 571 applications, Applicant respectfully submits that the statutory language does not clearly address whether a product reviewed under Section 571 of the FFDCA would be eligible for patent term extension. Should Section 571 of the FFDCA be construed to be part of a regulatory regime that is eligible for patent term extension under 35 U.S.C. §156(g) (for example, as a type of Section 512(b) application), Applicant believes it appropriate to refer to the dates of submission and approval of NADA 141-308 below.

To the extent Section 571 of the FFDCA can serve as a basis for patent term extension, Applicant respectfully submits that that the '055 patent should be eligible for an extension and estimates the extension to be **493 days**, the calculation of which is described below. Applicant

notes that the calculations provided below reflect the conditional approval of conditional NADA 141-308 on December 15, 2010. Should the delays based on regulatory review under Section 571 not be eligible for patent term extension under 35 U.S.C. §156(g), Applicants respectfully submit that the calculations provided in Sections A, B and C are not applicable and reserve the right to submit alternative calculations based on a subsequent Section 512(b) regulatory approval.

A. Eligibility:

(a) Pursuant to 35 U.S.C. § 156(a), the '055 patent claims a composition of the active ingredient;

(b) Pursuant to 35 U.S.C. § 156(a)(1), the term of the '055 patent has not expired before submission of this application for extension;

(c) Pursuant to 35 U.S.C. § 156(a)(2), the term of the '055 patent has never been extended;

(d) Pursuant to 35 U.S.C. § 156(a)(3), the application for extension is submitted by the owners of record of the '055 patent;

(e) To the extent Section 571 of the FFDCA can serve as a basis for patent term extension, Applicant respectfully submits that the approved product, sold under the trade name KINAVET-CA1, has been subject to a regulatory review period before its commercial marketing or use pursuant to 35 U.S.C. § 156(a)(4);

(f) To the extent Section 571 of the FFDCA can serve as a basis for patent term extension, Applicant respectfully submits that the permission for the commercial marketing or use of the product sold under the trade name KINAVET-CA1 after the regulatory review period is the first permitted commercial marketing or use of this product pursuant to 35 U.S.C. § 156(a)(5).

(g) Pursuant to 35 U.S.C. § 156(c)(4), no other patent has been extended for the same regulatory review period for the approved product sold under the trade name

KINAVET-CA1.

B. Regulatory Review Period:

(a) The period from **February 1, 2005** (as discussed above, the date a major health or environmental test on the drug was initiated or the date of an exemption under subsection (j) of section 512 of the FFDCA is at least on or around February 1, 2005, if not earlier) to July 9, 2010 (the date the conditional NADA under Section 571 was initially submitted) is 1984 days. To the extent Section 571 of the FFDCA can serve as a basis for patent term extension, Applicant respectfully submits that the "Testing Phase" should be1984 days pursuant to 37 C.F.R. § 1.778(c)(1).

(b) Pursuant to 37 C.F.R. § 1.778(c)(2), the period from July 9, 2010 (the date the conditional NADA under Section 571 was initially submitted) to December 15, 2010 (the date of NADA conditional approval) is 159 days. To the extent Section 571 of the FFDCA can serve as a basis for patent term extension, Applicant respectfully submits that the "Approval Phase" should be 159 days pursuant to 37 C.F.R. § 1.778(c)(2).

C. Extended Patent Term:

(a) The number of days in the regulatory review period described in section B above which were on and before September 9, 2008, the date on which the '055 patent issued, is 1316 days. Accordingly, 1316 days are subtracted from the regulatory review pursuant to 37 C.F.R. § 1.778(d)(1)(i).

(b) As demonstrated in Exhibit F, the Applicant acted with due diligence during the regulatory review period. Accordingly, zero (o) days are subtracted from the regulatory review period pursuant to 37 C.F.R. § 1.778(d)(1)(ii).

(c) To the extent Section 571 of the FFDCA can serve as a basis for patent term extension, one half of the number of days remaining in the Testing Phase (as calculated in Section B above) after the consideration of potential reductions pursuant to paragraphs (a) and (b) above is 334 days. Accordingly, 334 days are subtracted from the regulatory review period

pursuant to 37 C.F.R. § 1.778(d)(1)(iii). Applicants respectfully submit that after the above adjustments, the total remaining Testing Phase and Approval Phase is 493 days (334 days plus 159 days), should the delays based on regulatory review under Section 571 be eligible for patent term extension under 35 U.S.C. § 156(g).

(d) The period remaining in the term of the patent (set to expire August 1, 2023) measured from the date of conditional approval of the product sold under the trade name KINAVET-CA1 (December 15, 2010) (4612 days) when added to the period of extension (493 days) is 5105 days, which is less than fourteen (14) years. Accordingly, the fourteen (14) year limitation set forth in 37 C.F.R. § 1.775(d)(2)-(4) does not operate to reduce the regulatory review period.

(e) The period of extension (493 days) is less than five (5) years. Accordingly, the five (5) year limitation set forth in 37 C.F.R. § 1.778(d)(5)(i)(ii) does not operate to further reduce the regulatory review period.

(13) "A statement that applicant acknowledges a duty to disclose to the Director of the United States Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to any determination of entitlement to the extension sought."

Applicant acknowledges a duty to disclose to the Director of the United States Patent and Trademark Office and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought pursuant to 37 C.F.R. § 1.765.

As discussed above, Applicants respectfully submits that 35 U.S.C. § 156 and the associated regulations do not clearly address whether a product conditionally approved under Section 571 of the FFDCA would be eligible for patent term extension. Applicant is unaware of any prior decisions by the USPTO or the FDA addressing this particular issue and believes that this is one of first impression by for these regulatory agencies. Therefore, Applicant submits this application to request administrative determination of whether conditional approval of an animal drug under Section 571 of the FFDCA can serve as a basis for patent term extension.

(14) "The prescribed fee for receiving and acting upon the application for extension."

The prescribed fee for receiving and acting upon this application is believed to be $1,120.00 pursuant to 37 C.F.R. § 1.20(j)(1). A fee transmittal letter is attached to pay the application fee. The Commissioner is authorized to charge this fee and any additional required fees, or credit any overpayment, to Deposit Account No. 50-1088.

(15) "The name, address and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed."

Please direct all inquiries and correspondence relating to this application to:

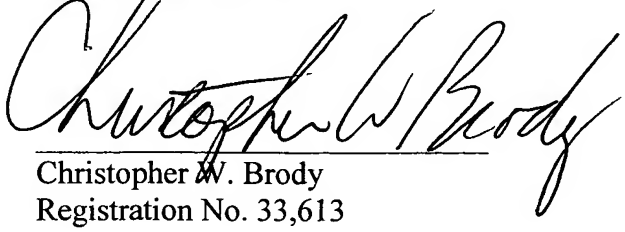
Christopher W. Brody
Clark & Brody
1700 Diagonal Road, Suite 510
Alexandria, VA 22314
Tel:(202)835-1753
Fax (703) 504-9415

A power of attorney (Exhibit J) is also enclosed so that the record will reflect correspondence should be addressed to Customer No. 22902.

(16) "The application under this section must be accompanied by two additional copies of such application (for a total of three copies)."

This Application is accompanied by two additional copies of such application for a total of three copies as required by 37 C.F.R. § 1.740(b). The undersigned attorney for Applicants hereby states that these copies are accurate and true duplicates of the original.

Respectfully submitted,
CLARK & BRODY



Christopher W. Brody
Registration No. 33,613

Customer No. 22902
1700 Diagonal Road, Suite 510
Alexandria, VA 22314
Telephone: 202-835-1111
Facsimile: 703-504-9415
Docket No.: 71247-0144
Date: February 11, 2011